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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,635	10/25/2000	Kestutis Tautvydas	11536-001001/55190USA8A	4398

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/696,635	Applicant(s) TAUTVYDAS ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-37 and 39-51 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-37 and 39-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2005 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed March 2, 2005, and amendment and response to the Final Office Action (mailed June 22, 2004), filed March 2, 2005 wherein claims 31-37, 39-49 have been amended and claims 50-51 are newly submitted; claims 38 is cancelled. Claims 1-30 are cancelled previously.

Currently, claims 31-37, 39-49 and 50-51 are pending in this application.

Claims 31-37, 39-49 and 50-51 are examined on the merits herein.

Again, Applicant's claim for domestic priority to provisional application Serial No. 60/167,250 filed 11/24/1999 under 35 U.S.C. 119(e) is acknowledged.

Applicant's remarks filed March 2, 2005 with respect to the rejection of claims 31-45 and 46-49 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, i.e., "wherein

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the monoester and the enhancer (comprising benzoic acid or salicylic acid) are present in an amount effective to provide a **synergistic** antimicrobial activity..." of record stated in the Office Action dated June 22, 2004 have been fully considered and found persuasive to remove the rejection since the specification, e.g., page 7, is seen to provide support for this limitation. Therefore, the said rejection is withdrawn.

Applicant's remarks filed March 2, 2005 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement for a **synergistic** antimicrobial activity produced by the claimed combination of a fatty acid monoester and benzoic acid or salicylic acid of record stated in the Office Action dated June 22, 2004 have been fully considered and found persuasive to remove. Therefore, the said rejection is withdrawn.

The following is the new ground(s) of rejection(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37, 39-49 and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitations "an enhancer comprising benzoic acid or salicylic acid" in claim 31, "the fatty acid monoester comprising glycerol monolaurate..." in claim 32, "the enhancer further comprises a chelating agent..." in claim 33, "the chelating agent comprises EDTA.." in claim 34, "two or more anionic surfactants comprises acyl lactylate salts..." in claim 37, "the vehicle comprises water, propylene glycol..." in claim 39, renders claims herein indefinite. According to the specification and claims as originally filed, an enhancer is or is selected from benzoic acid or salicylic acid", "the fatty acid monoester is glycerol monolaurate...", "the chelating agent is EDTA..", "two or more anionic surfactants is acyl lactylate salts...".

Note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. Thus, transitional phrase "comprising" is employed in a composition. In this case, the specification as originally filed fails to teach, for example, an enhancer comprising benzoic acid or salicylic acid.

Moreover, "a fatty acid monoester" such as glycerol monolaurate, is a known single and stable chemical compound, not a composition, not a moiety within a compound. Thus, one of ordinary skill in the art would not understand how a single compound would comprise a single compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-37, 39-49 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komp (US 5098694, PTO-892) in view of Andrews et al. (5,460,833 or 5,569,461, of record).

Komp discloses a natural deodorant composition comprising (i) the instant fatty acid monoester, glyceryl laurate (also known as glycerol monolaurate) in 0.5-5 wt %, 0.5-3 wt % or 0.5-1.5 wt %, within the claimed range herein (see abstract; col.1 line 63-68 to col.2 line 1-2); (ii) the instant enhancer, benzoic acid in 0.1-0.5 (see col.2 line 4-6), touching the claimed range herein; surfactants (emollients) such as PPG-15 stearyl ether, PPG-15 laureth 5, and PPG/PEG fatty alcohol ethers, in 2.0-10 wt % (see col.2 line 36-40, 64), overlapping the claimed range herein; a vehicle such as water in 0.1-50 wt% (see col.2 line 38), or alcohols, further comprising an acid, citric acid. See also claim 1.

Komp discloses that the natural deodorant composition therein possesses antimicrobial or antibacterial activities since bad odor is the result of bacterial or microbial actions (see col.1 lines 23-35).

Komp does not expressly disclose the employment of the anionic surfactants such as those in claim 37 herein; a chelating agent such EDTA; the particular alcohol, ethanol; the particular acid such as those in claim 35, in the deodorant or antimicrobial

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or antibacterial compositions therein. Komp does not expressly disclose the employment of a kit for comprising the composition therein.

Andrews et al. (5,460,833) discloses a similar antimicrobial composition comprising similar ingredients as Komp's composition, (i) the instant fatty acid monoester such as glycerol monolaurate, propylene glycol monolaurate, glycerol and propylene glycol monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim further comprising a chelating agent, EDTA, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, and all other instant acids, (iii) a food grade surfactant, anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; and a vehicle i.e., water and/or particular alcohols: propylene glycol and polyethylene glycol, or aqueous solution and ethanol (see abstract, col.2 lines 38-55, col.3 lines 1-8 and 35-38, col.4 lines 36-62, col.5 lines 4-13 and 20-39, and claims 1-9). Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide a synergistic antimicrobial activity, compared to used alone under the same condition (see col.2 lines 55-57 and col.3 lines 54-57). Hence, each of three major component alone is known to have antimicrobial activity. Andrews et al. also teaches that organic acids including the acids employed therein are known antimicrobial agents (see col.1 line 67 to col.2 line 7). Andrews et al. further discloses the compositions therein prepared by mixing the ingredients in the particular order (see col.5 lines 41 to col.6 line 5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such EDTA; the particular alcohol, ethanol; the particular acid such as such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, in the deodorant or antimicrobial or antibacterial compositions of Komp.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such EDTA; the particular alcohol, ethanol; the particular acid such as such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, in the deodorant or antimicrobial or antibacterial compositions of Komp, since Komp and Andrews et al. clearly disclose all ingredients as instantly claimed used in the deodorant or antimicrobial or antibacterial compositions. In particular, the composition of Komp is known to comprise all the same essential and critical ingredients as instantly claimed, (i) the instant fatty acid monoester, glyceryl laurate in 0.5-5 wt %, 0.5-3 wt % or 0.5-1.5 wt %, within the claimed range herein; (ii) the instant enhancer, benzoic acid in 0.1-0.5, touching the claimed range herein; surfactants in 2.0-10 wt %, overlapping the claimed range herein; a vehicle such as water in 0.1-50 wt%, or alcohols, further comprising an acid, citric acid.

Therefore, one of ordinary skill in the art would have found it obvious to employ the particular anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; a chelating agent such EDTA; the particular alcohol, ethanol; the particular

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acid such as such as lactic acid, tartaric acid, adipic acid, succininc acid, citric acid, in the deodorant or antimicrobial or antibacterial compositions, since all these agents are known and art-recognized surfactants, chelating agents, alcohols and acids and also known to be used in the similar antimicrobial or antibacterial compositions of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews et al. and Komp. Moreover, it is well known

Claims 31-33, 35-37, 39, 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse et al. (US 5968539, PTO-892).

Beerse et al. discloses a antimicrobial composition comprising (i) an antimicrobial active including glyceryl laurate (see col.5 line 20) in 0.001-5 wt %, (see also abstract) overlapping the claimed range herein; (ii) anionic surfactants herein (see col.8 line 41 to col.9 line 45), in 1-80 wt % (see col.2 line 36-40, 64), overlapping the claimed range herein; a vehicle such as water in 3-98.8 wt% (see col.2 line 38), (iii) a proton donating agent, an organic acid including salicylic acid, tartaric acid, adipic acid, succininc acid, citric acid in 0.1-12 wt%, overlapping the claimed range herein (see abstract, col.14 line 61-64); ethanol. See also claims 1-19; Examples at col. 24-28.

Beerse et al. does not expressly exemplify the composition comprising specific agents, glyceryl laurate and salicylic acid, as instantly claimed. Beerse et al. does not expressly disclose the employment of a kit for the composition therein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ specific agents, glyceryl laurate and salicylic acid, in the antimicrobial or antibacterial compositions of Beerse et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to specific agents, glyceryl laurate and salicylic acid, in the antimicrobial or antibacterial compositions of the prior art, since Beerse et al. disclose a reasonable expectation of success for all antimicrobial active listed in the patent, including glyceryl laurate, all organic acids including salicylic acid, tartaric acid, adipic acid, succinic acid, citric acid used in the antibacterial compositions therein, even though Beerse et al. does not exemplify glyceryl laurate and salicylic acid as preferred agents. It has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982)4 In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983).

Therefore, the motivation provided by the cited prior art herein to make the present invention is clearly present.

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Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Beerse et al.

Applicant's arguments filed March 2, 2005 with respect to the rejections made under 35 U.S.C. 103(a) of record in the previous Office Action June 22, 2004 have been considered but are moot in view of the new ground(s) of rejection above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-37, 39-49 and 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/659,571.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially same antimicrobial composition comprising the same or substantially same ingredients in the same or substantially same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-21 of copending Application No. 10/659,571.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 31-37, 39-49 and 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/936,989.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially same antimicrobial composition or kit comprising the same or substantially same ingredients in the same or substantially same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-25 of copending Application No. 10/936,989.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 31-37, 39-49 and 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/937,059.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same or substantially same antimicrobial composition or kit comprising the same or substantially same ingredients in the same or substantially same amounts.

Thus, the instant claims are seen to be obvious over the claims 1-25 of copending Application No. 10/936,989.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

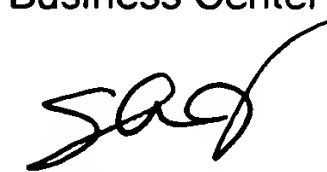
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
May 4, 2005